

WHAT IS CLAIMED IS:

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B17 ✓  
1. An implantable medical device comprising a body portion overlaid by a fabric overlayer, the body portion comprising a constituent material in intimate contact with a therapeutic agent, wherein the therapeutic agent is capable of being released from the body portion of the device.

✓ 2. The implantable medical device of claim 1, wherein the constituent material comprises at least one material selected from the group consisting of a polymer, a metal, a metal alloy, a body tissue, collagen, and a biosynthetic material.

✓ 3. The implantable medical device of claim 2, wherein the constituent material comprises a polymer selected from the group consisting of silicon, polyamide, polyimide, polycarbonate, polyether, polyester, a polyvinyl aromatic compound, polytetrafluoroethylene, poly(ethylene-chloro-trifluoroethylene), poly(ethylene-tetrafluoroethylene), poly(chloro-trifluoroethylene), a fluorinated ethylene-propylene copolymer, a perfluoroalkoxy copolymer, a fluoroelastomer, polyolefin, an ethylene-alpha olefin copolymer, an acrylic polymer, an acrylic copolymer, a vinyl halide polymer, a vinyl halide copolymer, a polyvinyl ether, a polyvinyl ester, a polyvinyl ketone, a polyvinylidene halide, polyacrylonitrile, a vinyl monomers homocopolymer, a vinyl monomer olefin copolymer, an acrylonitrile-styrene copolymer, an ABS resin, polysulfone, polyetherimide, polyetheretherketone, polyarylate, epoxy resin, liquid crystalline polymer, polyphenylene sulfide, polyphenylene oxide, polyamideimide, polyacetal, polyketone, polyarylate, an ethylene-vinyl acetate copolymer, and blends of the aforementioned polymers.

✓ 4. The implantable medical device of claim 3, wherein the polymer is selected from the group consisting of polyurethanes, silicones and combinations thereof.

5. The implantable medical device of claim 1, wherein the fabric overlayer comprises a knitted or woven fabric of polymer fibers.

6. The implantable medical device of claim 5, wherein the polymer fibers are selected from the group consisting of polyester, polyamide, polyurethane, polypropylene, polyethyleneterephthalate, poly(tetrafluoroethylene), polyethylene, poly(vinyl alcohol), polyacrylonitrile, poly(glycolic acid), poly(lactic acid), polydimethylsiloxane, aramid, and regenerated cellulose.

7. The implantable medical device of claim 5, wherein the polymer fibers comprise polyester.

8. The implantable medical device of claim 5, wherein the polymer fibers comprise polyethyleneterephthalate.

9. The implantable medical device of claim 1, wherein the therapeutic agent comprises an anti-inflammatory agent.

10. The implantable medical device of claim 9, wherein the anti-inflammatory agent is selected from the group consisting of cortisol, cortisone, fludrocortisone, prednisone, prednisolone, 6 $\alpha$ -methylprednisolone, triamcinolone, betamethasone, dexamethasone, beclomethasone, aclomethasone, amcinonide, clobetasol, clocortolone, gold thiomalate, gold thiosulfate, auranofin, D-penicillamine, rofecoxib, celecoxib, derivatives thereof, and salts thereof.

11. The implantable medical device of claim 10, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.

12. The implantable medical device of claim 9, wherein the therapeutic agent further comprises an antimicrobial agent.

13. The implantable medical device of claim 12, wherein the antimicrobial agent comprises at least one of rifampicin and gentamicin.

14. The implantable medical device of claim 1, wherein the therapeutic agent is coated onto the body portion of the device.

15. The implantable medical device of claim 1, wherein the therapeutic agent is compounded into the body portion of the device.

16. The implantable medical device of claim 1, wherein the body portion of the device comprises a liquid core comprising the therapeutic agent.

17. The implantable medical device of claim 1, wherein the therapeutic agent comprises an antimicrobial agent.

18. The implantable medical device of claim 1, selected from the group consisting of a prosthetic heart valve, an annuloplasty ring, a vascular graft, a sewing ring, a stent, a medical-electrical lead, an indwelling catheter, a pacemaker and a drug infusion pump.

19. The implantable medical device of claim 18, selected from the group consisting of a prosthetic heart valve, an annuloplasty ring, a vascular graft, and a sewing ring.

20. The implantable medical device of claim 1, wherein the fabric overlayer takes the form of a sheath, pouch, an encasement, an enclosure, a layer, a film, or a coating.

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21. A heart valve prosthesis comprising a sewing ring comprising a body portion comprising an biostable polymer in intimate contact with a therapeutic agent, said body portion overlaid by a polyester fabric overlayer.

✓ 22. The heart valve prosthesis of claim 21, wherein the biostable polymer is selected from the group consisting of polyurethanes, silicones and combinations thereof.

10 3 23. The heart valve prosthesis of claim 21, wherein the therapeutic agent comprises an anti-inflammatory agent selected from the group consisting of dexamethasone, a derivative thereof, or a salt thereof.

24. The heart valve prosthesis of claim 21, which is a bioprosthetic heart valve.

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25. A heart valve prosthesis comprising a sewing ring comprising a body portion comprising a metal or metal alloy in intimate contact with a therapeutic agent, said body portion overlaid by a polyester fabric overlayer.

therapeutic agent  
metal  
polyester

✓ 26. The heart valve prosthesis of claim 25, wherein the metal or metal alloy comprises at least one titanium and tantalum.

27. The heart valve prosthesis of claim 25, wherein the therapeutic agent comprises an anti-inflammatory agent selected from the group consisting of dexamethasone, a derivative thereof, or a salt thereof.

28. The heart valve prosthesis of claim 21, which is a mechanical heart valve.

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in case

29. In a bioprosthetic heart valve comprising a polymer insert containing struts attached to tissue leaflets to form a valve housing, wherein a fabric sheath encloses the polymer insert to form sewing ring, said sewing ring attached circumferentially to the base of the valve housing, the improvement comprising an releasable therapeutic agent in intimate contact with the polymer insert.

1.9 heart valve or annuloplasty ring ✓

30. The bioprosthetic heart valve of claim 29, wherein the polymer insert comprises silicone.

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31. The bioprosthetic heart valve of claim 30, wherein the polymer insert comprises radiopaque flexible silicone rubber.

32. The bioprosthetic heart valve of claim 29, wherein the therapeutic agent comprises an anti-inflammatory agent.

33. The bioprosthetic heart valve of claim 32, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.

34. The bioprosthetic heart valve of claim 29, wherein the therapeutic agent comprises an antimicrobial agent.

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35. The bioprosthetic heart valve of claim 29, wherein the flow occluder comprises pericardium or aortic root tissue from an animal.

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36. The bioprosthetic heart valve of claim 35, wherein the flow occluder comprises pericardium or aortic root tissue from a pig.

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ring 12  
37. In a mechanical heart valve comprising a metallic ringed valve housing containing a central metallic strut along which a flow occluder disk moves, wherein a fabric sheath encloses a metal insert to form a

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sewing ring, the improvement comprising a releasable therapeutic agent  
in intimate contact with constituent material of the insert. ✓

38. The mechanical heart valve of claim 37, wherein the metal insert  
comprises at least one of titanium and a titanium alloy.

39. The mechanical heart valve of claim 37, wherein the therapeutic  
agent comprises an anti-inflammatory agent.

40. The mechanical heart valve of claim 39, wherein the anti-  
inflammatory agent is dexamethasone, a derivative thereof, or a salt  
thereof.

41. An annuloplasty ring comprising a body portion overlaid by a  
polyester fabric overlayer, the body portion comprising an biostable  
polymer in intimate contact with an releasable therapeutic agent. |

42. The annuloplasty ring of claim 40, wherein the biostable polymer  
is selected from the group consisting of polyurethanes, silicones and  
combinations thereof.

43. The annuloplasty ring of claim 40, wherein the therapeutic agent  
comprises an anti-inflammatory agent selected from the group  
consisting of dexamethasone, a derivative thereof, or a salt thereof.

44. The annuloplasty ring of claim 40, wherein the therapeutic agent  
comprises an antimicrobial agent.

45. A method for replacing a heart valve in a patient comprising  
implanting a prosthetic heart valve into the patient, wherein the prosthetic  
heart valve comprises a sewing ring comprising a body portion

comprising a constituent material in intimate contact with a therapeutic agent, said body portion overlaid by a fabric overlayer.

46. The method of claim 45, wherein the constituent material of the body portion comprises a biostable polymer.

47. The method of claim 46, wherein the biostable polymer comprises a polymer selected from the group consisting of polyurethanes, silicones and combinations thereof.

48. The method of claim 45, wherein the constituent material of the body portion comprises a metal or a metal alloy.

49. The method of claim 46, wherein the metal or metal alloy comprises titanium.

50. The method of claim 45, wherein the therapeutic agent comprises an anti-inflammatory agent.

51. The method of claim 50, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.

52. A method for ameliorating the inflammatory response associated with heart valve replacement in a patient comprising implanting a prosthetic heart valve into the patient, wherein the prosthetic heart valve comprises a sewing ring comprising a body portion comprising a constituent material in intimate contact with a releasable anti-inflammatory agent, said body portion overlaid by a fabric overlayer.

53. The method of claim 52, wherein the fabric overlayer comprises polyester.

54. The method of claim 52, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.

55. The method of claim 52, wherein implantation of the prosthetic heart valve is accompanied by reduced pannus formation at the implant site.

56. A method for ameliorating the inflammatory response associated with heart valve repair in a patient comprising implanting an annuloplasty ring into the patient, wherein the annuloplasty ring comprises a body portion comprising a biostable polymer in intimate contact with a releasable anti-inflammatory agent, said body portion overlaid by a fabric overlayer.

57. The method of claim 56, wherein the fabric overlayer comprises polyester.

58. The method of claim 56, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.

59. The method of claim 56, wherein implantation of the annuloplasty ring is accompanied by reduced pannus formation at the implant site.

60. A method of making a medical sewing ring comprising:  
incorporating a therapeutic agent into an annular insert comprising a constituent material, such that the therapeutic agent is in intimate contact with the constituent material;  
enclosing the annular insert in a fabric sheath.

61. The method of claim 60, wherein the constituent material comprises a polymer.



62. The method of claim 61, wherein the constituent material comprises a biostable polymer.

63. The method of claim 62, wherein the biostable polymer is selected from the group consisting of polyurethanes, silicones and combinations thereof.

64. The method of claim 60, wherein the constituent material comprises a metal or a metal alloy.

65. The method of claim 64, wherein the metal or metal alloy is selected from the group consisting of titanium, tantalum, titanium alloys, cobalt chrome alloys, nickel chrome alloys, stainless steels, and combinations thereof.

66. The method of claim 60, wherein the fabric sheath comprises polyester.

67. The method of claim 60, wherein the therapeutic agent comprises an anti-inflammatory agent.

68. The method of claim 67, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.

69. The method of claim 60, wherein the therapeutic agent comprises an antimicrobial agent.

70. The method of claim 67, wherein the therapeutic agent further comprises an antimicrobial agent.

71. The method of claim 60, wherein incorporating a therapeutic agent into an annular insert comprises compounding the therapeutic agent into the annular insert.

72. The method of claim 60, wherein incorporating a therapeutic agent into an annular insert comprises coating the therapeutic agent onto the annular insert.

R 73. An implantable infusion pump comprising:  
a pump comprising an interior space for containment of a liquid;  
a delivery catheter for delivery of the liquid to a patient; and  
a polyester pouch surrounding the pump;  
said pump further comprising a constituent material in intimate contact with an anti-inflammatory agent, said anti-inflammatory agent capable of being released from the pump and eluting through the polyester pouch.

74. The implantable infusion pump of claim 73, wherein the anti-inflammatory agent is coated or adhered to the surface of the pump.

75. The implantable infusion pump of claim 74, wherein the anti-inflammatory agent is dexamethasone, a derivative thereof, or a salt thereof.